§ 522.542

parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

- (iv) Not for use in horses intended for food.
- (v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (e)(1) Specifications. The drug is a sterile aqueous solution. Each milliliter contains 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3 milligrams of dexamethasone).
- (2) Sponsor. See No. 059130 in §510.600(c) of this chapter.
- (3) Conditions of use. (i) The drug is given for glucocorticoid and anti-inflammatory effect in dogs and horses.
- (ii) Administer intravenously as follows: Dogs—0.25 to 1 milligram initially; may be repeated for 3 to 5 days or until response is noted. Horses—2.5 to 5 milligrams. If permanent glucocorticoid effect is required, oral therapy may be substituted. When therapy is to be withdrawn after prolonged use, the daily dose should be reduced gradually over several days.
- (iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.
- (iv) Do not use in viral infections. Anti-inflammatory action of corticosteroids may mask signs of infections. Except when used for emergency therapy, the product is contraindicated in animals with tuberculosis, chronic nephritis, cushingoid syndrome, or peptic ulcers.
- (v) Not for use in horses intended for food.
- (vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 522.542 Dexamethasone-21isonicotinate suspension.

- (a) Specifications. Each milliliter of sterile suspension contains 1 milligram of dexamethasone-21-isonicotinate.
- (b) *Sponsor*. No. 000010 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is used in the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.
- (2) It is recommended for intramuscular administration as follows: Dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—5 to 20 milligrams. Dosage may be repeated.
- (3) Clinical and experimental data have demonstrated that corticosteriods administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition following by dystocia, fetal death, retained placenta, and metritis.
- (4) Not for use in horses intended for food.
- (5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 37543, July 22, 1977, as amended at 47 FR 14703, Apr. 6, 1982]

§ 522.563 Diatrizoate meglumine and diatrizoate sodium injection.

- (a) Specifications. Diatrizoate meglumine and diatrizoate sodium injection contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium, in sterile aqueous solution.
- (b) Sponsor. See No. 053501 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) It is indicated for use in dogs and cats for visualization in excretion urography, including renal angiography, uretography, cystography. urethrography: and aortography; angiocardiography, peripheral arteriography, and venography; selective coronary artericerebral ography: angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.